

03-31-06

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**PATENT**  
**Docket No. P-279.00**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

VARADI, et al.

Serial No. 10/816,099

Filed: March 31, 2004

For: Kit For Measuring The Thrombin  
Generation in a Sample of a  
Patient's Blood or Plasma

Art Unit: 1651

Examiner: To be assigned

Date: March 29, 2006

**Information Disclosure Statement**

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior

art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicants have checked the appropriate boxes below.

- ☐ 1. This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.
  - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.  
37 C.F.R. § 1.97(e)(1).
  - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R.

§ 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

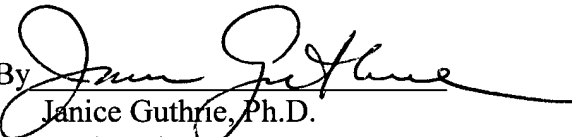
- ☐ c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Enclosed find our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p); in addition:
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☒ 4. The following document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement: **US 5,418,141; US 5,314,695; US 5,059,525; WO98/48283A1; WO93/07492A1; and Turecek et al.** Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.

- ☐ 5. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 6. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

**The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 02-1440 (P-279.00).**

Respectfully submitted,

By   
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In re application of: )  
VARADI, *et al.* )  
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Filed: March 31, 2004 )  
For: Kit For Measuring The Thrombin ) Examiner: To be assigned  
Generation in a Sample of a )  
Patient's Blood or Plasma )  
\_\_\_\_\_ )

**CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR §1.10**

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I hereby certify that the following documents:

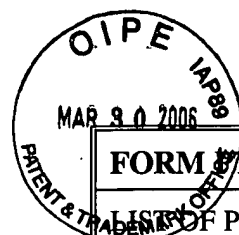
- 1) Information Disclosure Statement;
- 2) Form PTO-1449;
- 3) Copies of 3 cited references;
- 4) Copy of International Search Report for WO2005/095638; and
- 5) Post Card Receipt

are being deposited with the United States Postal Service as Express Mail, Label No. **EV 136970415 US** in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on **March 30, 2006**.

Respectfully submitted,

By *Diane Branham*  
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|  |                             |                        |
|--|-----------------------------|------------------------|
| <b>FORM PTO-1449 (Modified)</b>  | Docket No.: P-279.00        | Serial No.: 10/816,099 |
| <b>LIST OF PATENTS AND PUBLICATIONS<br/>FOR APPLICANT'S INFORMATION<br/>DISCLOSURE STATEMENT</b> | Applicant: VARADI, et al.   |                        |
|  | Filing Date: March 31, 2004 | Art Unit: 1651         |

**UNITED STATES PATENT DOCUMENTS**

| *Exr's.<br>Inits. | Ref.      | Patent No. | Date     | Name         | Class | Sub | Filing Date (if<br>applicable) |
|-------------------|-----------|------------|----------|--------------|-------|-----|--------------------------------|
|                   | <b>AA</b> | 5,418,141  | 05/23/95 | Zweig et al. |       |     |                                |
|                   | <b>AB</b> | 5,314,695  | 05/24/94 | Brown        |       |     |                                |
|                   | <b>AC</b> | 5,059,525  | 10/22/91 | Bartl et al. |       |     |                                |
|                   |           |            |          |              |       |     |                                |
|                   |           |            |          |              |       |     |                                |

**FOREIGN PATENT DOCUMENTS**

| Exr's. Init. | Ref       | Document No. | Date     | Country                              | Class | Sub | Translation?<br>Yes | No |
|--------------|-----------|--------------|----------|--------------------------------------|-------|-----|---------------------|----|
|              | <b>BB</b> | WO98/48283A1 | 10/29/98 | Instrumentation<br>Laboratory S.P.A. |       |     |                     |    |
|              | <b>BC</b> | WO93/07492A1 | 04/15/93 | Baxter Diagnostics Inc.              |       |     |                     |    |
|              |           |              |          |                                      |       |     |                     |    |
|              |           |              |          |                                      |       |     |                     |    |

**OTHER REFERENCES (Including Author, Date, Title, Pertinent Pages, Etc.)**

| Exr's.<br>Inits. | Ref.      | Bibliographic Data  |
|------------------|-----------|---|
|                  | <b>CA</b> | Turecek, P.L., et al. ; "Factor VIII Inhibitor-Bypassing Agents Act by Inducing Thrombin Generation and Can Be Monitored by a Thrombin Generation Assay"; <i>Pathophysiology of Haemostasis and Thrombosis</i> ; Vol. 33; pp. 16-22 (2003). |
|                  |           |   |
|                  |           |   |

|   |                 |
|---|-----------------|
| Examiner  | Date Considered |
| * Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. §609. Draw line through citation (i.e., citation) if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |